Attachment 1:

Supporting Data

Including Relevant Studies and Medical Literature

Inspiratory Impedance (e.g. ResQPOD) During Cardiac Arrest Bibliography

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Bahlmann L, Klaus S, et al. Brain metabolism during CPR assessed with microdialysis. Resuscitation 2003;59(2):255-60.

Frascone RJ, Bitz D, Lurie K. Combination of active compression decompression CPR and the inspiratory impedance threshold device: state of the art. Curr Opin Crit Care 2004;10(3):193-201.

Gabrielli A, Layon AJ, et al. Alternative ventilation strategies in CPR. Curr Opin Crit Care 2002;8(3):199-211.

Genzwuerker HV, Finteis T, et al. Influence of the impedance threshold valve (ITV) on ventilation with different airway devices. Abstract presented at ESA (Lisbon, Portugal; June 2004).

Langhelle A, Stromme T, et al. Inspiratory impedance threshold valve during CPR. Resuscitation 2002;52(1):39-48.

Lindner KH, Wenzel V. New mechanical methods for CPR. Literature study & analysis of effectiveness. Anaesthesist 1997;46:220-30.

Lurie K. Mechanical devices for CPR: an update. Emerg Med Clin North Am 2002;20(4):771-84.

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Lurie K. Bringing back the nearly dead. The hope and the challenge. Minn Med 2002;85(4):39-42.

Lurie KG, Lindner KH. Recent advances in CPR. J Cardiovasc Electrophysiol 1997;8(5):584-600.

Lurie K, Plaisance P, et al. Mechanical advances in CPR. Curr Opin Crit Care 2001;7(3):170-5.

Lurie K, Sukhum P, et al. Recent advances in mechanical CPR devices. Curr Opin Crit Care. 1999;5(3):184-192.

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Lurie KG, Barnes TA, et al. Evaluation of a prototypic inspiratory impedance threshold valve designed to enhance the efficiency of CPR. Respiratory Care 2003;48(1):52-57.

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Lurie KG, Voelckel WG, et al. Improving standard CPR with an inspiratory impedance threshold valve in a porcine model of cardiac arrest. Anesth Analg 2001;93(3):649-55.

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Nadkarni V, Srinivasan V, et al. Rapid brain cooling is enhanced with active compression decompression plus an inspiratory impedance threshold device CPR in a pig model of cardiac arrest. Circulation 2003;108(17):IV-379.

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Plaisance P, Soleil C, et al. Use of an inspiratory impedance threshold device on a facemask and endotracheal tube to reduce intrathoracic pressures during the decompression phase of active compression-decompression CPR. Crit Care Med 2005;33(5):990-4.

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The generally cleared indication for the ResQPOD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Studies are on-going in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss. The studies listed here are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

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- Aufderheide TP, Pirrallo RG, et al. Clinical evaluation of an inspiratory impedance threshold device during standard cardiopulmonary resuscitation in patients with out-of-hospital cardiac arrest. Crit Care Med. 2005 Apr;33(4):734-40.
- Pirrallo RG, Aufderheide TP, et al. Effect of an impedance threshold device on hemodynamics during conventional manual cardiopulmonary resuscitation. Resuscitation 2005; 66:13-20.
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- Plaisance P, Soleil C, et al. Use of an inspiratory impedance threshold device on a facemask and endotracheal tube to reduce intrathoracic pressures during the decompression phase of active compression decompression cardiopulmonary resuscitation. Crit Care Med 2005; 33(5):990-4.

Animal Studies

- Bahlmann L, Klaus S, et al. Brain metabolism during CPR assessed with microdialysis. Resuscitation 2003;59(2):255-60.
- Lurie KG, Coffeen P, et al. Improving active compression-decompression CPR with an inspiratory impedance valve. Circulation 1995;91(6):1629-32.
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* Some of the studies on this website page have been conducted with the ResQPOD. The presentation of these studies is not intended to imply outcome-based claims not yet cleared by the US Food and Drug Administration ("FDA"). These studies have been conducted for the purpose of supporting the clearance of future outcomes-based claims by the FDA.

The generally cleared indication for the ResQPOD is a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Click here to review the Instructions for Use. Studies are ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from

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1: Crit Care Med. 2006 Dec;34(12 Suppl):S466-73.

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Vital organ blood flow with the impedance threshold device.

Aufderheide TP, Lurie KG.

From the Department of Emergency Medicine, Medical College of Wisconsin, Milwaukee, WI (TPA); Advanced Circulatory Systems, Eden Prairie, MN (KGL); and the Department of Emergency Medicine, Hennepin County Medical Center, Minneapolis, MN (KGL).

OBJECTIVE:: The purpose of this study is to review cardiopulmonary resuscitation hemodynamics and vital organ blood flow in animal models with the use of the impedance threshold device (ITD) and to correlate these findings with the results of human clinical trials. RESULTS:: Animal studies have demonstrated near normalization of cerebral blood flow and an increase between 50% and 100% in cardiac blood flow with use of the ITD. Coincident coronary perfusion pressure is significantly increased with the ITD. Results of human clinical trials generally reflect the data seen in animal models, with near normal blood pressure during active compression-decompression cardiopulmonary resuscitation and the ITD, near doubling of blood pressure with standard cardiopulmonary resuscitation plus the ITD, and significantly increased short-term survival rates. CONCLUSIONS:: Improved vital organ perfusion with ITD use during cardiopulmonary resuscitation is an important advance in resuscitation. Incorporation of the ITD into protocols that improve other aspects of the care of patients during cardiac arrest and after successful resuscitation should result in further

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1: Resuscitation. 2005 Oct;67(1):103-8.

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Use of an impedance threshold device improves short-term outcomes following out-of-hospital cardiac arrest.

Thayne RC, Thomas DC, Neville JD, Van Dellen A.

Staffordshire Ambulance Trust, 70 Stone Road, Stafford, Staffordshire ST16 2TQ, UK. rcthayne@aol.com

INTRODUCTION: An impedance threshold device (ITD) has been developed for the treatment of cardiac arrest to augment circulation to the heart and brain during cardiopulmonary resuscitation (CPR). The ITD has ventilation timing lights that flash at 12 min(-1) to discourage excessive ventilation rates. HYPOTHESIS: Implementation of the ITD during conventional manual CPR in a large emergency medical services (EMS) system (Staffordshire, UK) is safe, feasible and will improve short-term survival. METHODS: ITD use was implemented by the Staffordshire Ambulance Trust, which treats 1600 cardiac arrests per year with 90 advanced life support (ALS) units and an average response time of 6.3 min. During training, rescuers learned to use the ventilation timing lights to discourage hyperventilation. Rescuers applied the device after tracheal intubation. They were trained to allow the chest to recoil fully after each compression. Prospective ITD use in adults receiving conventional manual CPR for non-traumatic cardiac arrest was compared to matched historical controls receiving conventional manual CPR without inspiratory impedance. All received similar ALS care. The

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The impact of a new CPR assist device on rate of return of spontaneous circulation in out-of-hospital cardiac arrest. [Prehosp Emerg Care. 2005]

Clinical evaluation of an inspiratory impedance threshold device during standard cardiopulmonary resuscitation in patients with out-of-hospital cardiac arrest. [Crit Care Med. 2005]

Effect of an inspiratory impedance threshold device on hemodynamics during conventional manual cardiopulmonary resuscitation. [Resuscitation. 2005]

primary endpoint was admission to the emergency department (ED) alive following cardiac arrest. Chi-square, Fisher's exact and Kolmogorov-Smirnov tests were used for statistical analyses. RESULTS: Survival (alive upon ED admission) in all patients receiving an ITD (61/181 [34%]) improved by 50% compared to historical controls (180/808 [22%]) (P<0.01). Survival in patients presenting in asystole tripled in the group receiving an ITD (26/76 [34%]) compared with historical controls (39/351 [11%]) (P=0.001). There were no significant adverse events. CONCLUSIONS: The ITD was used safely and effectively in a large, diverse EMS system and markedly improved short-term survival for adult patients in non-traumatic cardiac arrest.

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Clinical evaluation of an inspiratory impedance threshold device during standard cardiopulmonary resuscitation in patients with out-of-hospital cardiac arrest.

Aufderheide TP, Pirrallo RG, Provo TA, Lurie KG.

Department of Emergency Medicine, Medical College of Wisconsin, Milwaukee, WI, USA.

OBJECTIVE: To determine whether an impedance threshold device, designed to enhance circulation, would increase acute resuscitation rates for patients in cardiac arrest receiving conventional manual cardiopulmonary resuscitation. DESIGN: Prospective, randomized, double-blind, intention-to-treat. SETTING: Out-of-hospital trial conducted in the Milwaukee, WI, emergency medical services system. PATIENTS: Adults in cardiac arrest of presumed cardiac etiology. INTERVENTIONS: On arrival of advanced life support, patients were treated with standard cardiopulmonary resuscitation combined with either an active or a sham impedance threshold device. MEASUREMENTS AND MAIN RESULTS: We measured safety and efficacy of the impedance threshold device; the primary end point was intensive care unit admission. Statistical analyses performed included the chi-square test and multivariate regression analysis. One hundred sixteen patients were treated with a sham impedance threshold device and 114 patients

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Comparison of standard cardiopulmonary resuscitation versus the combination of active compression-decompression cardiopulmonary resuscitation and an inspiratory impedance threshold device for out-of-hospital cardiac arrest. [Circulation. 2003]

Evaluation of active compression-decompression CPR in victims of out-of-hospital cardiac arrest. [JAMA. 1994]

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were treated with an active impedance threshold device. Overall intensive care unit admission rates were 17% with the sham device vs. 25% in the active impedance threshold device (p = .13; odds ratio, 1.64; 95% confidence interval, 0.87, 3.10). Patients in the subgroup presenting with pulseless electrical activity had intensive care unit admission and 24-hr survival rates of 20% and 12% in sham (n = 25) vs. 52% and 30% in active impedance threshold device groups (n = 27) (p = .018, odds ratio, 4.31; 95% confidence interval, 1.28, 14.5, and p = .12, odds ratio, 3.09; 95% confidence interval, 0.74, 13.0, respectively). A post hoc analysis of patients with pulseless electrical activity at any time during the cardiac arrest revealed that intensive care unit and 24-hr survival rates were 20% and 11% in the sham (n = 56) vs. 41% and 27% in the active impedance threshold device groups (n = 49) (p = .018, odds ratio, 2.82; 95% confidence interval, 1.19, 6.67, and p = .037, odds ratio, 3.01; 95% confidence interval, 1.07, 8.96, respectively). There were no statistically significant differences in outcomes for patients presenting in ventricular fibrillation and asystole. Adverse event and complication rates were also similar. CONCLUSIONS: During this first clinical trial of the impedance threshold device during standard cardiopulmonary resuscitation, use of the new device more than doubled short-term survival rates in patients presenting with pulseless electrical activity. A larger clinical trial is underway to determine the potential longer term benefits of the impedance threshold device in cardiac arrest.

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1: Resuscitation. 2005 Jul;66(1):13-20.

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Effect of an inspiratory impedance threshold device on hemodynamics during conventional manual cardiopulmonary resuscitation.

Pirrallo RG, Aufderheide TP, Provo TA, Lurie KG.

Medical College of Wisconsin, Department of Emergency Medicine, 9200 W. Wisconsin Ave., FEH Room 1870, Milwaukee, WI 53226, USA. pirrallo@mcw.edu

BACKGROUND: In animals in cardiac arrest, an inspiratory impedance threshold device (ITD) has been shown to improve hemodynamics and neurologically intact survival. The objective of this study was to determine whether an ITD would improve blood pressure (BP) in patients receiving CPR for out-of-hospital cardiac arrest. METHODS: This prospective, randomized, double-blind, intention-to-treat study was conducted in the Milwaukee, WI, emergency medical services (EMS) system. EMS personnel used an active (functional) or sham (non-functional) ITD on a tracheal tube on adults in cardiac arrest of presumed cardiac etiology. Care between groups was similar except for ITD type. Low dose epinephrine (1mg) was used per American Heart Association Guidelines. Femoral arterial BP (mmHg) was measured invasively during CPR. RESULTS: Mean+/-S.D. time from ITD placement to first invasive BP recording was approximately 14 min. Twelve patients were treated with a sham ITD versus 10 patients with an active ITD. Systolic BPs (mean+/-S.D.) [number of patients treated at given time point] at T = 0 (time of first

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Combination of active compression decompression cardiopulmonary resuscitation and the inspiratory impedance threshold device: state of the art. [Curr Opin Crit Care. 2004]

Use of an inspiratory impedance threshold device on a facemask and endotracheal tube to reduce intrathoracic pressures during the decompression phase of active

arterial BP measurement), and T=2, 5 and 7 min were 85+/-29 [10], 85+/-23 [10], 85+/-16 [9] and 69+/-22 [8] in the group receiving an active ITD compared with 43+/-15 [12], 47+/-16 [12], 47+/-20 [9], and 52+/-23 [9] in subjects treated with a sham ITD, respectively ($p < 0.01$ for all times). Diastolic BPs at T = 0, 2, 5 and 7 min were 20+/-12, 21+/-13, 23+/-15 and 25+/-14 in the group receiving an active ITD compared with 15+/-9, 17+/-8, 17+/-9 and 19+/-8 in subjects treated with a sham ITD, respectively (p = NS for all times). No significant adverse device events were reported. CONCLUSIONS: Use of the active ITD was found to increase systolic pressures safely and significantly in patients in cardiac arrest compared with sham controls.

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compression-decompression cardiopulmonary resuscitation [Crit Care Med. 2005]

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1: Circulation. 2005 Aug 9;112(6):803-11. Epub 2005 Aug 1.

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Intrathoracic pressure regulator during continuous-chest-compression advanced cardiac resuscitation improves vital organ perfusion pressures in a porcine model of cardiac arrest.

Yannopoulos D, Nadkarni VM, McKnite SH, Rao A, Kruger K, Metzger A, Benditt DG, Lurie KG.

Department of Cardiology, Cardiac Arrhythmia Center, University of Minnesota, Minneapolis, MN, USA.

BACKGROUND: A novel device, the intrathoracic pressure regulator (ITPR), combines an inspiratory impedance threshold device (ITD) with a vacuum source for the generation of controlled -10 mm Hg vacuum in the trachea during cardiopulmonary resuscitation (CPR) while allowing positive pressure ventilation. Compared with standard (STD) CPR, ITPR-CPR will enhance venous return, systemic arterial pressure, and vital organ perfusion in both porcine models of ventricular fibrillation and hypovolemic cardiac arrest. METHODS AND RESULTS: In protocol 1, 20 pigs (weight, 30+/-0.5 kg) were randomized to STD-CPR or ITPR-CPR. After 8 minutes of untreated ventricular fibrillation, CPR was performed for 6 minutes at 100 compressions per minute and positive pressure ventilation (100% O2) with a compression-to-ventilation ratio of 15:2. In protocol 2, 6 animals were bled 50% of their blood volume. After 4 minutes of untreated ventricular fibrillation, interventions were

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The effects of positive end-expiratory pressure during active compression decompression cardiopulmonary resuscitation with the inspiratory threshold valve. [Anesth Analg. 2005]

Effects of active compression-decompression resuscitation on myocardial and cerebral blood flow in pigs. [Circulation. 1993]

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performed for 2 minutes with STD-CPR and 2 minutes of ITPR-CPR. This sequence was repeated. In protocol 3, 6 animals after 8 minutes of untreated VF were treated with ITPR-CPR for 15 minutes, and arterial and venous blood gases were collected at baseline and minutes 5, 10, and 15 of CPR. A newer, leak-proof ITPR device was used. Aortic, right atrial, endotracheal pressure, intracranial pressure, and end-tidal CO2 values were measured (mm Hg); common carotid arterial flow also was measured (mL/min). Coronary perfusion pressure (diastolic; aortic minus right atrial pressure) and cerebral perfusion pressure (mean arterial minus mean intracranial pressure) were calculated. Unpaired Student t test and Friedman's repeated-measures ANOVA of ranks were used in protocols 1 and 3. A 2-tailed Wilcoxon signed-rank test was used for analysis in protocol 2. Fischer's exact test was used for survival. Significance was set at $P<0.05$. Vital organ perfusion pressures and end-tidal CO2 were significantly improved with ITPR-CPR in both protocols. In protocol 1, 1-hour survival was 100% with ITPR-CPR and 10% with STD-CPR ($P=0.001$). Arterial blood pH was significantly lower and Paco2 was significantly higher with ITPR-CPR in protocol 1. Arterial oxygen saturation was 100% throughout the study in both protocols. Paco2 and Pao2 remained stable, but metabolic acidosis progressed, as expected, throughout the 15 minutes of CPR in protocol 3. CONCLUSIONS: Compared with STD-CPR, use of ITPR-CPR improved hemodynamics and short-term survival rates after cardiac arrest.

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1: Resuscitation. 2004 Apr;61(1):75-82.

ELSEVIER FULL-TEXT ARTICLE Links

Reducing ventilation frequency combined with an inspiratory impedance device improves CPR efficiency in swine model of cardiac arrest.

Yannopoulos D, **Sigurdsson G**, **McKnite S**, **Benditt D**, **Lurie KG**.

Department of Medicine, University of Minnesota (DY), Minneapolis, MN 55455, USA.

BACKGROUND: The basic premise that frequent ventilations during cardiopulmonary resuscitation (CPR) are a necessity for tissue oxygenation has recently been challenged. An inspiratory impedance threshold device (ITD) recently has also been shown to increase CPR efficiency, principally by augmenting circulation with little impact on ventilation. The optimal compression to ventilation (C/V) is not known for this new device. The purpose of this study was to compare the currently recommended C/V ratio of 5:1 with a 10:1 ratio, +/- the ITD, to optimize circulation and oxygenation during CPR. METHODS: Thirty-two adult pigs weighing 26-31 kg were randomized to CPR with varying C/V ratios +/- the ITD as follows: A = 5:1, B = 5:1+ITD, C = 10:1, D = 10:1+ITD. After 6 min of untreated ventricular fibrillation (VF), closed-chest standard CPR was performed with an automatic piston device that does not impede passive chest wall recoil, at a continuous compression rate of 100 min(-1). Synchronous breaths were given every 5 or 10 compressions during the decompression phase depending on the group. CPR was performed for 6 min and physiological variables

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Reducing ventilation frequency during cardiopulmonary resuscitation in a porcine model of cardiac arrest. [Resusc Care. 2005]

Intrathoracic pressure regulator during continuous-chest-compression advanced cardiac resuscitation improves vital organ perfusion pressures in a porcine model of cardiac arrest. [Circulation. 2005]

Optimizing standard cardiopulmonary resuscitation with an inspiratory impedance threshold valve. [Chest. 1998]

Rapid induction of cerebral hypothermia is enhanced with active compression-decompression plus inspiratory impedance threshold device cardiopulmonary resusitation in a porcine model of cardiac arrest. [J Am Coll Cardiol. 2006]

Combination of active compression decompression cardiopulmonary resuscitation and the inspiratory impedance threshold device: state of the art. [Curr Opin Crit Care. 2004]

were measured throughout the experimental protocol. RESULTS: A reduction in the frequency of ventilation from 5:1 to 10:1 resulted in significantly improved arterial and coronary perfusion pressure in a pig model of cardiac arrest. Addition of an ITD resulted in further increases in arterial and coronary perfusion pressures with both 5:1 and 10:1 C/V ratios, without compromising oxygenation. CONCLUSION: CPR efficiency can be optimized by changing the compression: ventilation ratio from 5:1 to 10:1 and with concurrent use of the inspiratory threshold device.

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1: Resuscitation. 2002 Jan;52(1):39-48.

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Inspiratory impedance threshold valve during CPR.

Langhelle A, Stromme T, Sunde K, Wik L, Nicolaysen G, Steen PA.

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The use of an inspiratory impedance threshold valve (ITV) during cardiopulmonary resuscitation (CPR) should reduce intrathoracic pressure during natural chest recoil or active chest decompression. This might in turn improve venous return and thereby organ blood flow. The haemodynamic effects during both standard CPR and active compression-decompression (ACD)-CPR with and without the ITV, therefore, were studied in a well-established porcine model with cross-over design. Sixteen pigs were randomised to one of four methods initially, changing the method every fifth minute during mechanical chest compression at 100 min(-1). Myocardial blood flow was doubled when the valve was added to standard CPR, median (q25-q75) 14 (3-47) versus 27 (9-51) ml min(-1) 100 g(-1) (P=0.001). ACD-CPR caused a similar increase, while adding the ITV to ACD-CPR only tended to increase myocardial blood flow (P=0.077). Varying the technique had no effect on cerebral, kidney or carotid blood flow, coronary perfusion pressure, expired CO(2) concentrations or blood gases. The valve is a promising new tool in CPR, but more independent studies of the device are

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Vasopressor response in a porcine model of hypothermic cardiac arrest is improved with active compression-decompression cardiopulmonary resuscitation using the inspiratory impedance threshold valve. [Anesth Analg. 2002]

Improving active compression-decompression cardiopulmonary resuscitation with an inspiratory impedance valve. [Circulation. 1998]

The effects of positive end-expiratory pressure during active compression decompression cardiopulmonary resuscitation with the inspiratory threshold valve. [Anesth Analg. 2003]

Effects of active compression-decompression cardiopulmonary resuscitation with the inspiratory threshold valve in a young porcine model of cardiac arrest. [Pediatr Res. 2002]

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1: Crit Care Med. 2000 Nov;28(11 Suppl):N207-9.

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Improving the efficiency of cardiopulmonary resuscitation with an inspiratory impedance threshold valve.

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In an effort to improve the efficiency of cardiopulmonary resuscitation (CPR), a new inspiratory impedance threshold valve has been developed to enhance the return of blood to the thorax during the chest decompression phase. This new device enhances negative intrathoracic pressure during chest wall recoil or the decompression phase, leading to improved vital organ perfusion during both standard CPR and active compression-decompression CPR. With active compression-decompression CPR, addition of the impedance threshold valve results in sustained diastolic pressures of >55 mm Hg in patients in cardiac arrest. The new valve shows promise for patients in asystole or shock refractory ventricular fibrillation, when enhanced return of blood flow to the chest is needed to "prime the pump." The potential long-term benefits of this new valve remain under study.

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Optimizing standard cardiopulmonary resuscitation with an inspiratory impedance threshold valve. [Chest. 1998]

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Evaluation of a prototypic inspiratory impedance threshold valve designed to enhance the efficiency of cardiopulmonary resuscitation. [Respir Care. 2003]

Inspiratory impedance threshold valve during CPR. [Resuscitation. 2002]

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1: Emerg Med Clin North Am. 2002 Nov;20(4):771-84.

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Mechanical devices for cardiopulmonary resuscitation: an update.

Lurie K.

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Despite the promise and universal use of the Kouwenhoven technique for closed chest cardiac massage, this method has been shown repeatedly to suffer from lack of clinical efficacy. Although the Kouwenhoven technique can clearly save lives, the inherent inefficiency of this approach and the challenges related to teaching and retaining the skills needed to perform the technique correctly have limited its overall effectiveness. This has prompted the development of newer lifesaving CPR techniques and devices. Some of the advances, such as the vest approach, active compression-decompression, and the impedance threshold valve, offer a benefit when compared with the Kouwenhoven technique. It is clear, however, that challenges related to implementation of these newer approaches will determine their ultimate utility. It is not sufficient to have a better technique or device available. Challenges to implementation of the newer approaches include overcoming the inertia of a universal mindset on the already-familiar Kouwenhoven technique and creating a cost-effective justification for change. Each year, approximately 10 million people in the United States are trained in the Kouwenhoven technique.

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[New mechanical methods for cardiopulmonary resuscitation (CPR). Literature study and analysis of effectiveness]. Anaesthesist. 1997]

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Active chest compression-decompression for cardiopulmonary resuscitation. Cochrane Database Syst Rev. 2004]

Alternative cardiopulmonary resuscitation devices. Curr Opin Crit Care. 2002]

Mechanical devices for cardiopulmonary resuscitation. Curr Opin Crit Care. 2005]

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Americans spend nearly $500,000,000 annually on this form of CPR training and retraining. Given the less than 5% survival rate for the 300,000 patients who experience out-of-hospital cardiac arrest each year in the United States, the prudence of this societal investment when compared with other ways health care dollars are spent should be questioned. It is hoped that this mismatch between costs and benefits will be recognized and will lead to the adoption of more effective means to resuscitate patients.

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1: Resuscitation. 2000 May;44(3):219-30.

ELSEVIER FULL-TEXT ARTICLE Links

Use of an inspiratory impedance threshold valve during cardiopulmonary resuscitation: a progress report.

Lurie K, Voelckel W, Plaisance P, Zielinski T, McKnite S, Kor D, Sugiyama A, Sukhum P.

Cardiac Arrhythmia Center, Cardiovascular Division, University of Minnesota, Minneapolis 55455, USA. lurie002@tc.umn.edu

Building upon studies on the mechanism of active compression-decompression (ACD) cardiopulmonary resuscitation, a new inspiratory impedance threshold valve has been developed to enhance the return of blood to the thorax during the decompression phase of CPR. Use of this device results in a greater negative intrathoracic pressure during chest wall decompression. This leads to improved vital organ perfusion during both standard and ACD CPR. Animal and human studies suggest that this simple device increases cardiopulmonary circulation by harnessing more efficiently the kinetic energy of the outward movement of the chest wall during standard CPR or active chest wall decompression. When used in conjunction with ACD CPR during clinical evaluation, addition of the impedance valve resulted in sustained systolic pressures of greater than 100 mmHg and diastolic pressures of greater than 55 mmHg. The new valve may be beneficial in patients in asystole or shock refractory ventricular fibrillation, when enhanced return of blood flow to the chest is needed to 'prime the pump'. The potential long-term benefits of this

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The effects of positive end-expiratory pressure during active compression decompression cardiopulmonary resuscitation with the inspiratory threshold valve. [Anesthesiology. 2001]

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new valve remain under investigation.

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RESQPOD® CIRCULATORY ENHANCER FREQUENTLY ASKED QUESTIONS

MECHANISM OF ACTION IN PATIENTS REQUIRING ASSISTED VENTILATION, FOR EXAMPLE, DURING CPR

1. How does the ResQPOD Circulatory Enhancer improve circulation during cardiopulmonary resuscitation (CPR)?

The ResQPOD, an impedance threshold device (ITD), utilizes the interdependence of the body's respiratory and circulatory systems to create a vacuum (negative pressure) within the chest during the recoil phase of CPR, which follows each chest compression. The ResQPOD regulates the influx of respiratory gases into the chest during the chest wall recoil (relaxation or decompression) phase, which lowers the intrathoracic pressure and draws more venous blood back to the heart. Improved blood return to the heart (preload) results in improved blood flow out of the heart (cardiac output) during the subsequent compression. Thus, despite its placement into the ventilation circuit, the ResQPOD is a circulatory enhancer device that works during chest compressions, specifically during the chest wall recoil phase of CPR.

2. What are the intrathoracic pressure levels found during inspiration in a healthy, spontaneously breathing person compared to the decompression phase of CPR in a cardiac arrest patient receiving standard CPR alone and to a patient receiving CPR in conjunction with the ResQPOD Circulatory Enhancer?

Average negative intrathoracic pressures:

- In a healthy, spontaneously breathing person at rest are approximately -1 to -3 mmHg;
- In a cardiac arrest patient who is receiving standard CPR, varies between approximately 0 to -2 mmHg
- In a cardiac arrest patient who is receiving CPR with the ResQPOD varies between approximately -3 to -8 mmHg depending upon the elastic recoil properties of the chest.

The greater the negative intrathoracic pressure (vacuum), the more blood that returns to the heart. In addition, the lower intrathoracic pressure causes a decrease in intracranial pressure. However, it should be noted that excessive negative pressures can be detrimental. The ResQPOD has been specifically designed to safely optimize the degree of negative pressure in order to increase blood flow to the heart and brain.

3. How do negative and positive pressures within the lungs influence blood flow within the thoracic cavity?

The impedance threshold device (ITD) physiology is based on the principle that changes in intrathoracic pressure are transmitted rapidly to the heart and other organs in the chest. This physiology was initially discovered by Mueller, who showed that when someone takes a breath or inspires against a closed glottis (Mueller Maneuver), this results in an abrupt and marked decrease in pressure within the plural space, which is instantaneously transmitted to the right heart. This results in a marked enhancement in venous return back to the heart.

Although initially contra-intuitive, using an ITD during CPR is based upon the same principle; that is, when the chest wall recoils the pressure inside the lungs (and the thorax across the board) decreases to sub-atmospheric pressure, thus creating a vacuum relative to the rest of the body. This negative pressure is immediately transmitted to the right heart, just as in the Mueller Maneuver, and venous return is enhanced. Intracranial pressure is also instantaneously lowered because of the connection between the thorax and the pair of vertebral sinuses along

the spinal cord. This can be seen in the pig video (produced by ACSI) at the point in the video where the narrator points out how low the right atrial pressure goes when the ITD is added to the circuit. Lowered intrathoracic pressures translate into lowered right atrial pressures, resulting in an enhanced venous return and greater coronary perfusion pressures.

4. How do I know if the ResQPOD is working?

The ResQPOD works by increasing circulation. All ResQPODs are 100% tested prior to shipment to assure they are properly functioning. Measurements of blood flow and circulation must be made indirectly, especially in a patient undergoing CPR. The best and most rapid way to know the device is working is to measure end tidal carbon dioxide ($ETCO_2$), an indirect measure of circulation. When $ETCO_2$ is increased, it usually means that more blood is circulating; as blood passes through the lungs, more CO_2 is removed proportionally to the increase in blood flow. Typically, $ETCO_2$ increases by about 30% in a patient treated with the ResQPOD. This equates to a near doubling of blood flow to the heart. For the best comparison, you should measure $ETCO_2$ prior to placement of the ResQPOD, and then about 3 minutes later. It sometimes takes up to 15 minutes to achieve maximum $ETCO_2$ levels once the ResQPOD is in place. It is important to note that we do not advise taking time to measure $ETCO_2$ prior to use of the ResQPOD as it only delays the benefit to the device. However, for those who want to see a difference, and thus know the ResQPOD is working, this is one way to measure it.

Another indirect way to assess the increase in circulation is to look at survival rates. Since relatively few patients actually live for 24 hours after an out-of-hospital cardiac arrest and fewer survive to discharge, you would need to look at a large number of cardiac arrests before you will see a statistically significant increase in survival rates. We have performed several studies to prove that the ResQPOD increases survival rates. For example, in a Milwaukee (WI) EMS study[6], in 111 patients who presented in an arrest rhythm with some electrical activity (ventricular fibrillation, pulseless ventricular tachycardia, pulseless electrical activity), there was a 94% increase in survival for those patients who received an ITD. We recommend a minimum of 100 patient uses before determining if there is a trend towards a clinical benefit. This approach has worked well in a number of cities, including Stafford, England. With 100 patients, you should see an increase in the number of patients who survive short-term. Much larger numbers are needed to demonstrate improvement in long-term survival with neurologic improvement.

Yet another way to see the increase in circulation is to measure blood pressure or the strength of the pulse. The invasive blood pressure should be significantly higher with the ResQPOD and in general, rescuers report feeling a stronger pulse with the ResQPOD.

Finally, how well the ResQPOD works can vary somewhat from patient to patient as there are other variables that contribute to the ResQPOD's effectiveness (e.g. chest wall compliance, quality of CPR performed, etc.).

5. Is the ResQPOD effective with standard and active compression decompression (ACD) CPR? What about mechanical CPR devices (e.g. AutoPulse or Thumper)?

The combination of animal and human studies have shown statistically significant improvements in blood pressure, vital organ circulation and survival rates from cardiac arrest and normal neurological function when an impedance threshold device is used in conjunction with standard

and ACD CPR.[1,2,3,4,5,6,7,8,9,10] It can be used with any method of CPR that uses traditional types of airway adjuncts. The manufacturer has experience in using an ITD with the Thumper (Michigan Instruments) in animals and the LUCAS device (Jolife) in humans with success.

6. Does the ResQPOD interfere with the patient's ability to exhale?
No, the ResQPOD provides insignificant resistance to patient exhalation. Expired air leaves the patient through the ventilation port.

7. Does the ResQPOD limit the rescuer's ability to ventilate the patient?
No, the patient may be freely ventilated, at whatever compression to ventilation ratio and tidal volume the situation dictates.

8. Is hyperventilation helpful during CPR?
The natural tendency when performing CPR is to ventilate the patient frequently, either inadvertently or intentionally. Contrary to common practice, hyperventilation is very detrimental during CPR and in the newly resuscitated patient. Each extra breath interferes with the development of negative intrathoracic pressure created during the chest wall recoil (or decompression) phase. The 2005 American Heart Association (AHA) guidelines state "*Rescuers should not provide hyperventilation (too many breaths or too large a volume). Excessive ventilation is unnecessary and is harmful because it increases intrathoracic pressure, decreases venous return to the heart, and diminishes cardiac output and survival.*[11]
Thus, hyperventilation, that is, ventilation more often than 10 times/minute, markedly reduces the efficiency of all methods of CPR, with or without the ResQPOD. Hyperventilation, with or without the ResQPOD, inhibits blood flow back to the heart by preventing the development of the intrathoracic vacuum and venous return to the heart during the decompression phase of CPR. This is a fundamental point that must be heavily emphasized when training rescuers on how to perform any method of CPR and use the ResQPOD.

9. What if $ETCO_2$ levels are elevated, either during CPR or right after a pulse has returned? Shouldn't I hyperventilate in those cases?
No, hyperventilation reduces circulation and therefore compromises the elimination of carbon dioxide. Improved circulation (from less ventilation) will tend to correct acid-base imbalance. If $ETCO_2$ levels are elevated, it can be a sign that cardiac output is improved or that a spontaneous pulse has returned. In the absence of known blood gases, there are no data to support that hyperventilation is good for elevated $ETCO_2$ levels and plenty of data to suggest that hyperventilation is bad for circulation. If you observe a very low arterial pH after return of

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[1] The generally cleared indication for the ResQPOD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Studies area on-going in the US to evaluate the long-term benefit of the ResQPOD for specific indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss. The references in this communication is not intended to imply specific outcome-based claims not yet cleared by the US FDA.
[2] Plaisance P, et al. Crit Care Med 2005;33:990-994.
[3] Wolcke BB, et al. Circulation 2003;108:2201-2205.
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[8] Thayne R, et al. Resuscitation 2005;67:103-108.
[9] Lurie KG, et al. Anesth Analg 2001;93(3):649-55
[10] Lurie KG, et al. Circulation 2002;105(1):124-9
[11] 2005 AHA Guidelines for CPR and ECC. *Circulation*. 2005;112:IV-22.

spontaneous circulation, then you should consider using sodium bicarbonate rather than increased ventilation rates to help raise the pH, assuming the blood pressure is stable.

10. Will the ResQPOD hinder patients who begin to breathe spontaneously?
Patients who begin to breathe on their own will have to overcome the "opening pressure" of the ResQPOD's resistance regulation system (approx. -10 cmH_2O) before air will be allowed to enter the device. For this reason, the ResQPOD should be removed immediately from the respiratory circuit when chest compressions are no longer required and the breathing should be supported as indicated.

11. What effect does altitude have on the ResQPOD Circulatory Enhancer's function; i.e. can it be used in aero medical or submarine environments?
No effect. Altitude does not effect on the ResQPOD's performance.

12. What effect will breath stacking (delivering a series of breaths without compressions in between) have on the ResQPOD's function?
Breath stacking will increase pressures in the chest, inhibit venous return, and when performed with the ResQPOD, will delay the effect of the ResQPOD, as the pressure within the chest is higher after breath stacking. It is for that reason that the 2005 AHA guidelines recommend a 30:2 compression to ventilation ratio for patients with an unsecured airway (e.g. facemask). Breaths should be delivered over 1 sec for both unsecured (e.g. facemask) and secured airways (e.g. ET tube). In intubated patients, we recommend a 10:1 compression to ventilation ratio (equivalent to 10 ventilations/minute at the AHA-recommended compression rate of 100/min), which is consistent with AHA Guidelines.[11]

13. Silicone valves are known to stick when they become warm and wet from respiration – especially diaphragm valves. Does the ResQPOD Circulatory Enhancer remain functional in extreme temperatures and humidity?
Yes, the ResQPOD has been tested under extreme temperature and humidity conditions and remains functional as indicated in the product's packaging and labeling.

FEATURES

14. I've been doing CPR on the job for years, why should I use the timing assist lights?
Ventilating at the proper rate is critical to the success during CPR, with or without the ResQPOD. Even among experienced rescuers, 10 breaths/minute seems slow as there is a natural tendency to ventilate patients too frequently during cardiac arrest. While proper ventilation is important, hyperventilation diminishes the opportunity for the ResQPOD to be effective, because each time you give a breath, you destroy the vacuum that is being created in the chest during chest compressions. Studies have shown that even the most experienced healthcare providers perform proper CPR only about 20% of the time and that devices that provide rate guidance lead to a significant improvement in technique. The timing assist lights are designed to encourage a ventilation rate of 10/minute, which is consistent with the 2005 AHA guidelines for patients with a secured airway. The timing assist lights also provide the rescuer with guidance on how rapidly to compress the chest. Rescuers should compress the chest 10 times for each light flash (10 compressions every 6 seconds = 100 compressions/min). The timing light function is not linked in any way to the device's inspiratory impedance feature, so, if for some reason the timing lights fail to blink, the device still provides inspiratory impedance.

15. If the timing assist lights flash at 10/min (at 6 second intervals), how do I use them during CPR with an unsecured airway?

The timing assist lights are really intended to promote the proper rate during ventilation with a secured airway, where it is recommended that compressions and ventilations are performed asynchronously (independent of each other). During CPR with a facemask, rescuers are encouraged to perform CPR with the ResQPOD in place but without using the timing assist lights to guide ventilations. Minimal interruptions in chest compression result in enhanced circulation. The person performing chest compressions should count out loud to 30, then pause compressions to allow 2 ventilations. Ventilations more often than every 30 compressions are NOT recommended.

16. Does the battery in the ResQPOD create an environmental disposal issue?

The timing assist lights on the ResQPOD are powered by a lithium battery and do not pose an overall environmental threat. When you are through using the ResQPOD, leave the timing lights on to drain the battery then dispose of the ResQPOD as you would lithium batteries. Check individual country regulations regarding disposal.

17. Does the ResQPOD provide positive end expiratory pressure (PEEP)?

No. One animal study has shown that low levels of PEEP may improve the efficiency of CPR with the ResQPOD[12] but there are no human studies evaluating both the ResQPOD and PEEP to date.

18. Can the ResQPOD be reused?

No, the ResQPOD is a single patient use product and is marked with the ISO international symbol for single use. The number of parts and their tight specifications, along with the various material components do not allow the ResQPOD to be disassembled, disinfected and reassembled for reuse.

19. It has been demonstrated that flow rates above 40 lpm can cause gastric distension when using a bag-valve mask. Does the ResQPOD Circulatory Enhancer limit ventilation flow rates to less than 40 lpm?

No, there is no significant airflow resistance through the ResQPOD during ventilation by the rescuer. Care must be taken to avoid high pressures during rescuer-assisted ventilations and to limit the duration of the breath to 1 second/breath (until chest rise).

20. How much inspiratory impedance does the ResQPOD provide?

The valving mechanism within the ResQPOD creates a selective resistance to the influx of air until a pressure of approximately -10 cmH_2O (-7.36 mmHg) is reached, at which time the valves open to allow respiratory gases in.

21. What is the ResQPOD's shelf life?

Three years from the date of manufacture.

22. What is the dead space of the ResQPOD?

The ResQPOD's dead space is 40.7 ml.

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[12] Voelckel WG, et al. Anesth Analg 2001;92(4):967-74

23. What should we do if the patient starts gasping?
Gasping represents a primitive brainstem reflex that draws air into the lungs, venous blood back to the heart, and lowers intracranial pressures. Continue to use the ResQPOD if the patient is gasping as long as the patient requires CPR (i.e. severe hypotension).

24. Can the ResQPOD be used with one or two-person CPR?
Yes, the key to success with the ResQPOD in an unintubated patient is using it with a good facemask seal. With two rescuers, one should focus solely on maintaining a good seal with the ResQPOD in place while the other person compresses the chest. Either the chest compressor or the person holding the facemask can squeeze the bag. A facemask head strap can be used with either one or two-person CPR to also help maintain the seal.

INDICATIONS/CONTRAINDICATIONS

25. The ResQPOD is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonary hypertension, aortic stenosis, flail chest, chest pain and shortness of breath. What does this mean for patients in cardiac arrest?
Patients in cardiac arrest do not have enough blood pressure to support life. Regardless if they have a prior history of other medical conditions (e.g. heart failure or hypertension), when in cardiac arrest they have only one major medical problem that must be corrected or they will die. Blood flow and circulation during cardiac arrest are known to be poor. For patients who are in need of circulatory support because they are in cardiac arrest and receiving CPR, you can use the ResQPOD as a circulatory enhancer. The ResQPOD is not contraindicated in patients in cardiac arrest receiving CPR. These patients have an 80 - 90% or more chance of dying secondary to low circulation due to cardiac arrest, which is their primary medical problem. One can use the ResQPOD to help treat this primary problem. Once that problem has been effectively treated, then the ResQPOD may no longer be indicated or appropriate in view of other medical conditions, such as the listed contraindications; thus, we recommend removing it when not performing CPR, once a pulse has been obtained. The prescribing physician should make the final determination about when the ResQPOD is used.

26. Is chest trauma a contraindication for use of the ResQPOD Circulatory Enhancer?
The only trauma-related contraindications to ResQPOD use is a flail chest. Since the ResQPOD is used to enhance circulation, the device also should not be used in patients with ongoing uncontrolled hemorrhage.

27. What effect will the ResQPOD Circulatory Enhancer have during resuscitation on patients with an open or closed pneumothorax?
Any "leak" in the chest cavity will interfere with the generation of negative pressures. In patients with open pneumothoraces, rescuers are taught to cover the wound with a one-way seal that allows air to escape from the chest but not to enter. Assuming there is a one-way flap in place, the ResQPOD will not affect an open pneumothorax. In a closed pneumothorax, positive pressure ventilation is dangerous, but we are not aware of any mechanism by which the ResQPOD could significantly worsen a closed pneumothorax.

28. Does the ResQPOD Circulatory Enhancer have any effect on intracranial pressure and are there any specific recommendations for patients with head injuries?

In animal models of cardiac arrest, use of an ITD lowers intracranial pressure and results in overall improvement in cerebral perfusion pressures.[13] Though the ResQPOD has not been specifically tested in patients with head injuries, the manufacturer is not aware of any contraindications for use in patients with head injuries.

29. Can I use the ResQPOD Circulatory Enhancer on children?

The AHA guidelines recommend adult CPR procedures for patients ages 8 years and above. The ResQPOD should be effective in patients of all ages; however, it has only been tested clinically in adults ages 18 years and above. Animal studies in a pediatric model of cardiac arrest, have demonstrated that the ResQPOD very effectively enhances circulation in 10 kg piglets in cardiac arrest.[14] If there is a good seal between the airway device (e.g. ET tube) and the lungs, the ResQPOD works well. As long as there is an adequate seal during positive pressure ventilation, the ResQPOD should work effectively. It is the ultimate decision of the prescribing physician to determine in what ages of patients the ResQPOD should be used.

30. I've noticed that the ResQPOD adds some height and weight to the ventilation circuit. If my patient is intubated, should I be concerned at all about the tube dislodging?

The ResQPOD does add some height and weight to the ventilation circuit. For this reason, ACSI strongly recommends that the rescuer use a commercially available tube restraint device when using the ResQPOD. We do not advocate using tape for this purpose. Prior to attaching the ResQPOD, the tube's placement should be confirmed. The same care should be taken with the ResQPOD as when using a resuscitator bag alone: secure the tube well and reassess tube placement frequently.

31. The directions for use state that prolonged use for more than 30 minutes is not recommended. Why is this?

The ResQPOD is a 510(k) cleared device with an intended use for patients who can benefit from an increase in blood circulation. This includes patients with low blood pressure who may need assisted ventilation, such as those in cardiac arrest, as well as patients with low blood pressure who are spontaneously breathing, such as those suffering from severe dehydration. Although it has a broad indication for use, the ResQPOD Circulatory Enhancer is optimized for use in patients who require assisted breathing. A different ACSI product with the same regulatory clearance and utilizing the same technology is optimized for use in patients who are spontaneously breathing.

The reference to prolonged use in the directions is intended to ensure that if a spontaneously breathing patient does use the ResQPOD, the patient does not become fatigued during use. Patients using the ResQPOD with assisted ventilation, such as cardiac arrest patients, will not tire from use of the ResQPOD after 30 minutes as they are not breathing on their own.

32. Why do you recommend that the ResQPOD be removed immediately after the return of spontaneous circulation in cardiac arrest patients?

While cardiac arrest patients may be able to breathe on their own through the ResQPOD upon return of spontaneous circulation, the work of breathing may be too much for them to tolerate given their fragile state immediately after the return of spontaneous circulation. In addition,

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[13] Yannopoulos D, et al. Resuscitation 2004;(61):75-82.
[14] Voelckel WG, et al. Pediatr Res 2002;51(4):523-7.

once a pulse returns and CPR is no longer being performed, the device has served its purpose for a cardiac arrest patient.

COMPATIBILITY WITH OTHER ADJUNCTS/PROCEDURES

33. Does the ResQPOD Circulatory Enhancer comply with International Standard Organization (ISO) anaesthetic connection standards?

Yes, the ResQPOD is in full compliance of ISO 5356-1, Anaesthetic and respiratory equipment – conical connectors.

34. What effect does adding a PEEP valve to the ventilation circuit (distal or proximal) have on the ResQPOD Circulatory Enhancer?

PEEP is compatible with the ResQPOD. If it is used, it should be placed between the ResQPOD and the ventilation source, not between the ResQPOD and the airway. One animal study has shown that low levels of PEEP may improve the efficiency of CPR with the ResQPOD[12], but there are no human studies evaluating both the ResQPOD and PEEP to date. Nonetheless, we do not recommend the use of PEEP in patients undergoing CPR, with or without the ResQPOD.

35. What effect does adding continuous positive airway pressure (CPAP) to the ventilation circuit (distal or proximal) have on the ResQPOD?

CPAP is not compatible with the ResQPOD because it is not possible to lower intrathoracic pressure with CPAP. CPAP is contraindicated during CPR as it decreases venous blood flow back to the heart. CPAP should not be used during the performance of CPR, with or without the ResQPOD.

36. What effect does adding bi-level positive airway pressure (BiPAP) to the ventilation circuit (distal or proximal) have on the ResQPOD Circulatory Enhancer?

BiPAP is not compatible with the ResQPOD because any continuous positive airway pressure ventilation negates most of the effects of the ResQPOD during cardiac arrest.

37. Can I use the ResQPOD Circulatory Enhancer with a colormetric end tidal carbon dioxide ($ETCO_2$) detector in the ventilation circuit to assess endotracheal (ET) tube placement or with a bag-valve resuscitator that incorporates $ETCO_2$ detection as a feature (e.g. Capno-Flo [Mallinkrodt])?

Yes. The colormetric test results may be more positive with the ResQPOD in place if the ET is in the proper position. Place the colormetric $ETCO_2$ detector between the ResQPOD and the ventilation source, making sure all connections are tight and do not leak.

38. Can I use electronic $ETCO_2$ detection (with sidestream or mainstream gas sampling) in the same ventilation circuit as the ResQPOD Circulatory Enhancer?

Yes, as long as the sensor is placed between the ResQPOD and the ventilation source and not between the ResQPOD and the airway, which could create an air leak and, therefore, hinder the development of the vacuum. This is especially true with sidestream sampling devices. If a sidestream sampling sensor is placed between the airway adjunct and the ResQPOD, it causes a loss of vacuum and will negate the ResQPOD's effect. Some electronic $ETCO_2$ sensors (depending on brand) may not fit into the ventilation circuit above the ResQPOD without a 15/22 mm adaptor. One inexpensive source for these 15/22 mm adaptors is: Qosina; phone: 631-242-

3000; fax: 631-242-3230; website: www.qosina.com; product name: Straight connector; 22 mm OD/18 mm ID x 15 mm OD/10 mm ID; part #50101.

39. Can I use the ResQPOD Circulatory Enhancer with bag-valve resuscitators that have an integrated "mediport" (feature that permits administration of medications via a metered dose inhaler) or to administer medications endotracheally (e.g. Medibag, Ambu)?

Yes, the ResQPOD should not affect the delivery of the medication and the medication should not affect the performance of the ResQPOD. However, this has not been clinically tested and may depend upon the medication used. If you are delivering endotracheal medications without a mediport, the manufacturer recommends that you disconnect the ResQPOD from the endotracheal (ET) tube, administer the medications directly into the ET tube, and then reconnect the ResQPOD.

40. Can I use a drug atomizer with the ResQPOD?

The ResQPOD does not need to be removed when the atomizer is securely connected between the ResQPOD and the ET tube.

41. Can the ResQPOD Circulatory Enhancer be used with a bag-valve resuscitator with a feature that limits flow rates (and thus airflow pressures) during ventilation (e.g. SMART BAG)?

Yes. This feature will not affect the ResQPOD's function.

42. Can I use the ResQPOD with automatic (transport or other) ventilators?

Yes, the ResQPOD can be used with most automatic ventilators. The only brand that we are aware of that is not compatible with the ResQPOD is the Oxylator. In the automatic mode, the Oxylator provides a continuously positive airway pressure that is harmful for the patient, with or without the ResQPOD. This continuously positive airflow interferes with the ResQPOD's ability to create a vacuum (negative pressure). ACSI and the American Heart Association believe that use of the automatic mode of an oxygen powered, flow-limited resuscitator (e.g. Oxylator) should be avoided because it applies "*continuous PEEP that is likely to impede cardiac output during chest compressions (Class III)*".[15]

43. Can the ResQPOD Circulatory Enhancer be used on a patient with a tracheostomy or stoma?

A patient with a stoma could have an endotracheal tube placed into the stoma for airway management. If there is not a good seal between the airway device and the lungs, the ResQPOD may be less effective. As long as there is an adequate seal during positive pressure ventilation, the ResQPOD should work effectively. It is the ultimate decision of the prescribing physician to determine whether the ResQPOD should be used in these types of patients.

44. Can the ResQPOD Circulatory Enhancer be used on an uncuffed endotracheal tube?

If there is not a good seal between the airway device and the lungs, the ResQPOD may be less effective. As long as there is an adequate seal during positive pressure ventilation, the ResQPOD should work effectively. It is the ultimate decision of the prescribing physician to determine what airway adjuncts the ResQPOD should be used with.

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[15] 2005 AHA Guidelines for CPR and ECC. *Circulation.* 2005;112:IV-48.

45. Can the ResQPOD Circulatory Enhancer be used with any standard facemask?
Yes; however, the manufacturer strongly recommends that the user consider the quality of the facemask to use it with. Obtaining and maintaining an adequate seal during facemask ventilation is critically important to the generation of the all-important vacuum. Many standard facemasks purchased today are selected primarily based upon cost, not mask quality. ACSI recommends that anyone who is going to use the ResQPOD on a facemask use one with excellent face-sealing qualities. A 2-handed ventilation technique, as recommended by the American Heart Association, is preferred.

The new model of ResQPOD no longer requires a 15/22 mm adaptor in order to attach it to a standard facemask and an adaptor is no longer supplied with the ResQPOD. A special sticker on the packaging notifies the user that an adaptor is no longer required.

46. I see that the ResQPOD can be used for mouth-to-mask ventilation, but the ResQPOD doesn't come packaged with a mouthpiece. How can I get one?
Most mouthpieces with standard 22 mm OD adaptors will work. One inexpensive source for mouthpieces that will work with the ResQPOD is: Tri-anim (www.tri-anim.com); Name: mouthpiece, standard, 22 mm OD; part #371-1005.

47. Can I use the ResQPOD Circulatory Enhancer on a Combitube, laryngeal mask airway (LMA), esophageal obturator airway (EOA), Cobra, King or other advanced airway?
The ResQPOD is cleared for use on airway adjuncts used during assisted ventilation. The ResQPOD will fit on these advanced airway devices and should be effective as long as there is a sufficient seal within the ventilation circuit.

48. Has the ResQPOD Circulatory Enhancer been tested with semi-open anesthetic circuits (e.g. Bain, McGill, Lack) as these are used in emergency resuscitation rooms connected to resuscitation machines?
The ResQPOD has not been tested in semi-open anesthetic circuits; however, there is no known reason that the ResQPOD should not work with these machines.

49. Has the ResQPOD Circulatory Enhancer been tested with Soda Lime Absorber "Closed Circuit" anesthetic systems, which are also used in resuscitation areas?
The ResQPOD has not been tested in closed circuit anesthetic systems; however, there is no reason to believe that the ResQPOD would not work.

50. When expiration release pressures are high, minute volume dividers and pressure-cycled resuscitators may respond with a high respiratory rate and low breath volumes. Most EMS ventilators and BVM devices can be fitted with a break valve pressure of between 45 and 60 cmH_2O. Does this affect ResQPOD performance?
This should not alter the performance of the ResQPOD.

51. Does the application of cricoid pressure interfere with ResQPOD performance?
No.

REGULATORY QUESTIONS

52. Has the AHA made any recommendations on the ResQPOD?
Yes, an impedance threshold device (e.g. ResQPOD) is recommended with a Class IIa level recommendation in the recently released 2005 AHA guidelines for CPR and emergency cardiac care.[16] There are no other impedance threshold devices on the market besides the ResQPOD.

The American Heart Association feels that, ideally, all CPR and ECC recommendations should carry a Class I or Class IIa level of recommendation. In their guidelines they state: "*For Class IIa recommendations, the weight of evidence supports the action or therapy and the therapy is considered acceptable and useful.*"[17]

53. Does the ResQPOD Circulatory Enhancer have 510(k) clearance from the FDA?
Yes; the ResQPOD Circulatory Enhancer is indicated for home, hospital, clinic and emergency care use, for the temporary increase in blood circulation as directed by a physician or licensed practitioner. The ResQPOD Circulatory Enhancer can be used in patients requiring assisted ventilation, for example, patients receiving CPR. It is contraindicated in dilated cardiomyopathy, congestive heart failure, pulmonary hypertension, aortic stenosis, flail chest, chest pain and shortness of breath. It can be used with a facemask, endotracheal tube or other appropriate airway adjunct used for assisted ventilation.

54. Does the ResQPOD Circulatory Enhancer, Cardiac Arrest have the CE mark?
Yes.

55. Who is your regulatory representative in the EU?
The regulatory representative for Advanced Circulatory Systems, Inc. is CEPartner4U, 3951DB;13.NL, telephone: +31(0) 6516.536.26.

SALES-RELATED QUESTIONS

56. How do I buy the ResQPOD?
The ResQPOD is available for purchase exclusively through Tri-anim. Please contact your local Tri-anim representative or call 1-800-TRI-ANIM (800-874-2646) or go to www.tri-anim.com.

[16] 2005 AHA Guidelines for CPR and ECC. *Circulation.* 2005;112:IV-48.
[17] 2005 AHA Guidelines for CPR and ECC. *Circulation.* 2005;112:IV-2.

COMPANY-RELATED QUESTIONS

57. I've seen references to CPRx and ResQSystems. Are these the same company as Advanced Circulatory Systems?

Yes, the company, when founded in 2000, was named CPRx LLC. In 2002, the name changed to ResQSystems and in 2003 the company incorporated and assumed the current name, Advanced Circulatory Systems, Inc. (ACSI).

58. I've seen the term impedance threshold valve (ITV) and other names for this product. Are they the same?

Yes, you may see references in the studies that have been published to impedance threshold valve (ITV), Resuscitator Valve, Resusci-Valve, and ResQValve. These are essentially earlier versions of the same product with the same functionality. ACSI currently generically refers to devices that provide inspiratory impedance as impedance threshold devices (ITDs), of which the company manufactures two versions with the brand names: 1) ResQPOD® Circulatory Enhancer, intended for use in assisted ventilation applications, and 2) ACSI Circulatory Enhancer, intended for use in spontaneously breathing applications.

59. Are there other impedance threshold devices on the market?

No, the only ITD on the market is the ResQPOD by ACSI.

60. I've heard that ACSI also manufactures a product called the ResQPump. Where can I get one?

The ResQPump is a hand-held device used to perform active-compression decompression (ACD) CPR. It is not currently available for sale in the United States. A large clinical trial (ResQ Trial) involving the use of the ResQPump and ResQPOD began in the Fall of 2005, but the study is being conducted with permission of the Food and Drug Administration (FDA). The ResQPump can be purchased for use outside the United States from Advanced Circulatory Systems by calling 952-947-9590.

TRAINING QUESTIONS

61. Do you sell a training version of the ResQPOD?

Currently no; however, the battery will usually power the lights on the device for many hours or even days if the battery is properly preserved. If you use a ResQPOD for training, be sure to replace the clear plastic tab that secures the ON-OFF switch in the OFF position once training is completed. This will preserve battery function for many repeated uses during training. ResQPODs that are used for training purposes should not be used on real patients.

62. What other training aids are available?

Advanced Circulatory Systems has a product training kit, the *ResQTrainer Kit*, which is available from Tri-anim. Please contact your local Tri-anim representative or call 1-800-TRI-ANIM (800-874-2646).

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ACSI Circulatory Enhancer

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Clinical Information

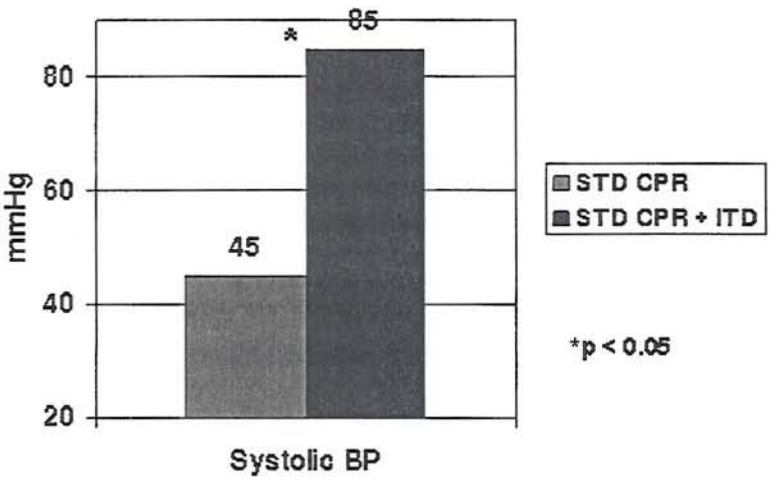
The ResQPOD Circulatory Enhancer – Cardiac Arrest has been proven in clinical trials conducted in France, Germany, the United Kingdom and the United States to:

- **Be Safe and Effective**
- **Increase Blood Pressure**
- **Increase Cardiac Output**
- **Increase the Opportunity for Survival from Cardiac Arrest**
- **Improve the Opportunity for Complete Neurological Recovery**

Click here to see a Key Study Summary for the ResQPOD

Increases Blood Pressure

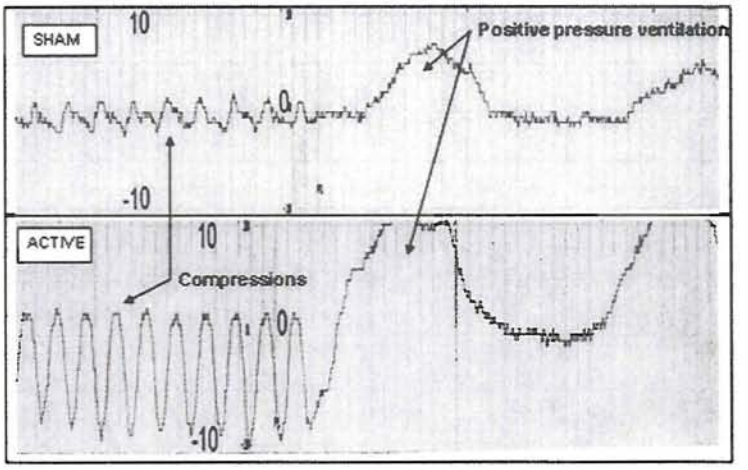
Effect of the ResQPOD on Blood Pressure in Humans Receiving CPR



Pirrallo et al. Resuscitation 2005; 66:13-20

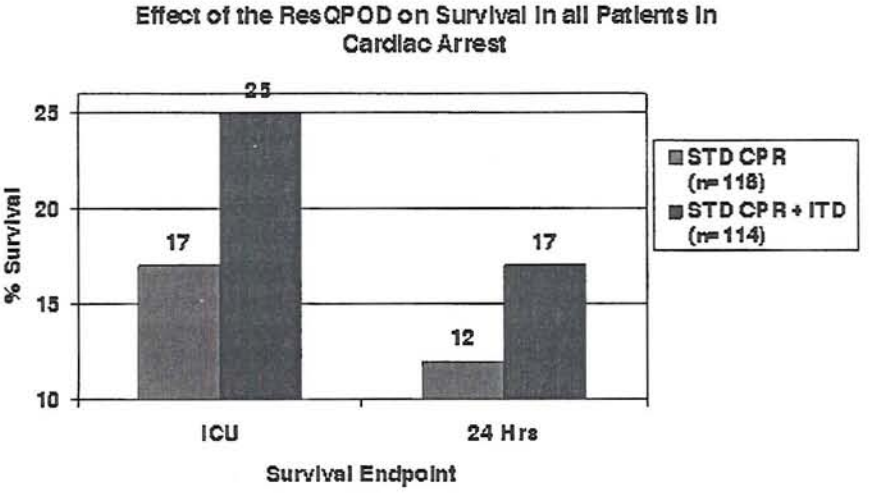
Increases Cardiac Output

Example of how inspiratory impedance enhances the intrathoracic vacuum (negative pressure [mmHg]) in humans undergoing ACD CPR with an active vs. sham ResQPOD on a facemask



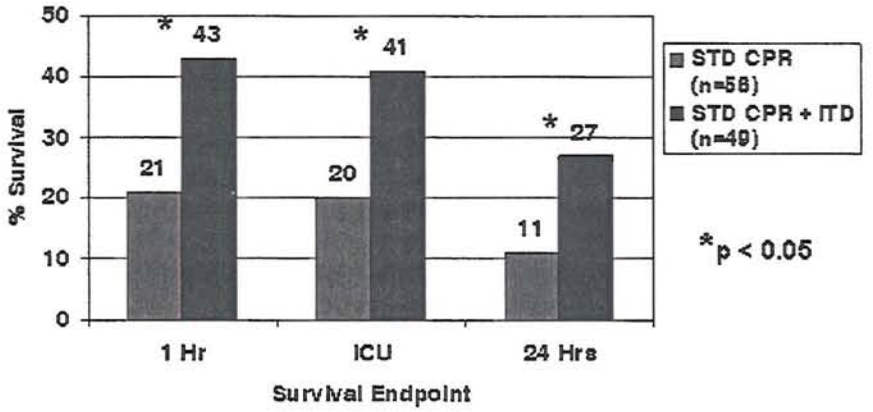
Plaisance et al. Crit Care Med 2005;33(5):990-994.

Increases Opportunity for Survival



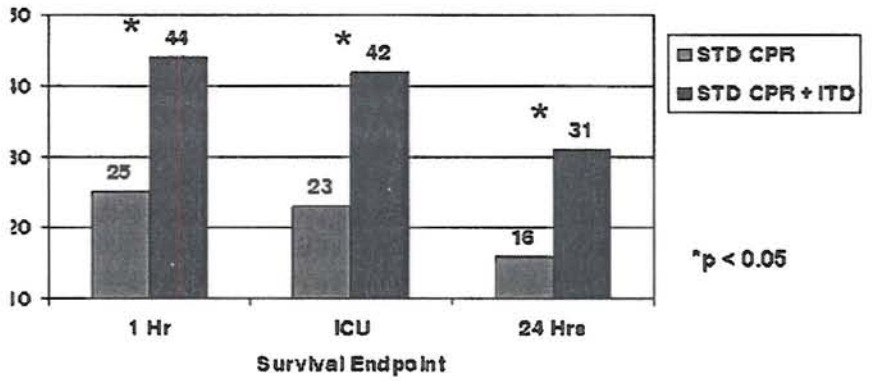
Aufderheide et al. Crit Care Med 2005;33(4):734-40.

Effect of the ResQPOD on Survival in Patients with PEA at Any Time During Cardiac Arrest
(46% of all patients)



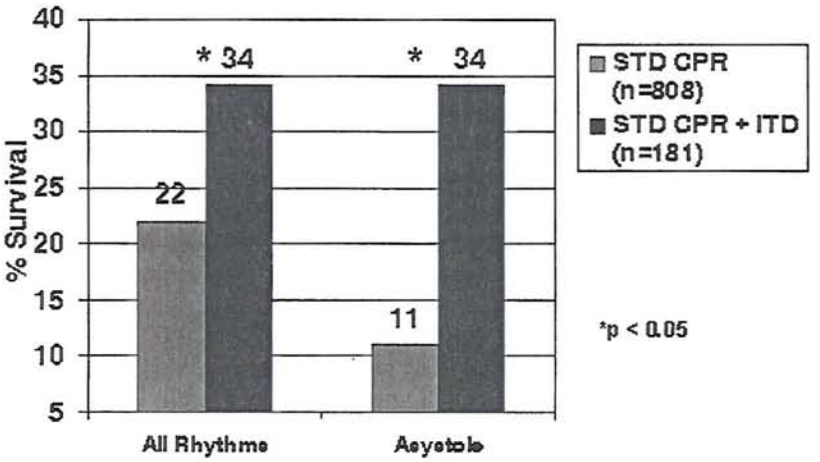
Aufderheide et al. Crit Care Med 2005;33(4):734-40.

Effect of ResQPOD on Survival in Patients Presenting with Cardiac Arrest Rhythm Other than Asystole (VF/VT/PEA)
(46% of all patients)

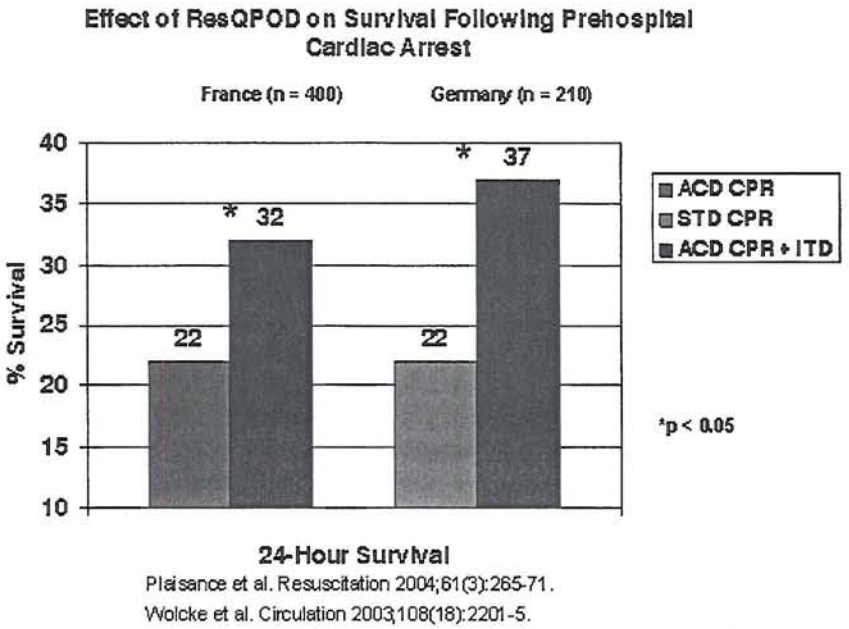


Aufderheide et al. Crit Care Med 2005;33(4):734-40.

Effect of ResQPOD on Survival to the Emergency Department Following Prehospital Cardiac Arrest

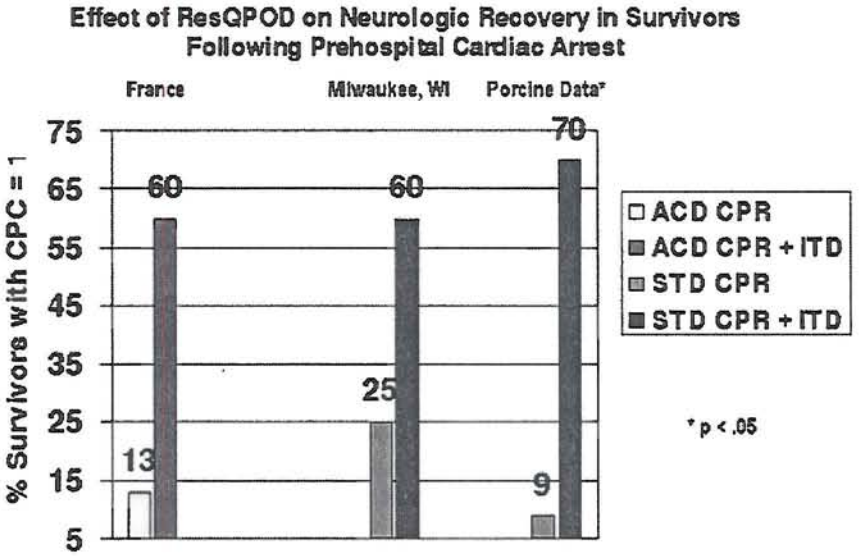


Thayne et al. Resuscitation 2005;in press.



Plaisance et al. Resuscitation 2004;61(3):265-71.
Wolcke et al. Circulation 2003;108(18):2201-5.

Improves Opportunity for Complete Neurological Recovery



Plaisance et al. Resuscitation 2004;61(3):265-71.
Aufderheide. Crit Care Med 2005;33(4):734-40.
Lurie et al. Circulation 2002; 105 124-129

The generally cleared indication for the ResQPOD is a temporary increase in blood

circulation during emergency care, hospital, clinic and home use. Click here to review the Instructions for Use. Studies are ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss.

For more information on completed clinical studies click here. The references on this website are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

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American Heart Association Guidelines

The impedance threshold device (e.g., ResQPOD) is recommended as a Class IIa device in the 2005 American Heart Association CPR Guidelines. [1]

This device is now more highly recommended than any other device or drug used by emergency personnel for increasing circulation during CPR & for improving resuscitation rates.

2005 AHA Guidelines

for patients in cardiac arrest

Devices/Level of Recommendation

Impedance Threshold Device (ResQPOD®)	**IIa**
Vest CPR	IIb
Mechanical Piston	IIb
ACD CPR	IIb

Drugs/Level of Recommendation

Epinephrine	IIb
Amiodarone	IIB
Vasopressin	Indeterminate
Lidocaine	Indeterminate
Atropine	Indeterminate

Click here for a recent press release regarding the 2005 Guidlelines.

Click here for a recent communication from the AHA's Director of Training regarding the ResQPOD.

[1] 2005 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care; Circulation 2005; Vol: 112, Issue 24 Supplement; Dec. 13 2005.

The generally cleared indication for the ResQPOD is a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Click here to review the Instructions for Use. Studies are ongoing in the United States to evaluate the

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ACSI Circulatory Enhancer

Home

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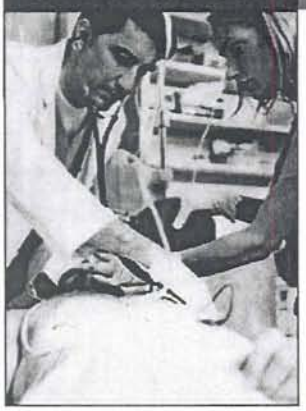

Sudden Cardiac Arrest

The ResQPOD ® Circulatory Enhancer

Learn about the technology behind the ResQPOD.

Sudden Cardiac Arrest is:

- The leading cause of death among adults in developed countries worldwide.
- Experienced by more than a million people annually.

Sudden Cardiac Arrest is almost always fatal:

- 95% of the victims of cardiac arrest do not survive despite receiving cardiopulmonary resuscitation (CPR).
- Many of the remaining 5% have poor neurological outcomes.
- CPR alone delivers only 25% of normal blood flow to the brain and 15% of normal blood flow to the heart.
- Maintaining adequate blood flow to vital organs is the key to patient survival and quality of life.

The generally cleared indication for the ResQPOD is a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Click here to review the Instructions for Use. Studies are ongoing in the United States to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest, hypotension during dialysis and severe blood loss.

For more information on completed clinical studies click here. The references on this website are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

Attachment 2:

Recommended Policies/Procedures to

be Instituted RE:

Use;

Medical Control;

Treatment Protocols, and;

Quality Assurance of

Procedure/Medication/Device

ResQPOD Protocol

Purpose and Rationale:

Two provider agencies in Alameda County, Alameda County Fire and Hayward Fire, will compare the ResQPOD circulatory enhancer with conventional CPR. This trial study will be conducted to demonstrate possible benefits of this device for use in EMS throughout Alameda County.

Methodology:

The trial will be a prospective non-randomized clinical trial that will evaluate conventional manual CPR with the use of the ResQPOD, compared to historical controls from database: adult non-trauma cardiopulmonary arrest patients receiving conventional manual CPR only.

Duration:

The study will be conducted for a **six month** period of time (April 1, 2007 – September 30, 2007) to ensure effectiveness and safety of the ResQPOD

Indication:

The ResQPOD will be used on all adult patients who sustain a non-traumatic cardiac arrest or had sustained a non-traumatic cardiac arrest upon arrival of providers. In all patients, CPR will be performed as usual according to the current 2005 American Heart Association guidelines.

Contraindications:

The following are contraindications for the use of the ResQPOD:
Dilated cardio myopathy, congestive heart failure, pulmonary hypertension, flail chest, aortic stenosis, chest pain, shortness of breath. Obviously, the patients may not be able to provide a history of these conditions. The device should not be used if family members or friends provide a history of any of the above conditions. The device should be removed upon the return of spontaneous circulation (ROSC). While it is probably acceptable for breathing patients, it is not designed to do so. The device may / should be replaced if the patient subsequently loses pulses.

Training:

All paramedics will be oriented to the ResQPOD using the training materials provide by Alameda County EMS and the manufacturer. Providers will attend a two hour course that will in-service them on the ResQPOD, as well as review the 2005 American Heart Association Guidelines for CPR, and ultimately how they work together. The training will entail a written exam and skills competency test.

Procedure:

The Alameda County Fire Department and Hayward Fire Department Paramedics will provide conventional CPR with the ResQPOD to **ALL non-traumatic cardiopulmonary arrest patients that are presumed to be 12 years of age or older.** All patients must meet Alameda County criteria for resuscitation efforts. Special attention will be directed to meeting the current 2005 American Heart Association standards for number and volume of ventilations and number and depth of chest compressions for CPR. The Auto Pulse or any other CPR adjuncts will **not** be used for the study patients.

Paramedics will intubate the cardiac arrest patient as per Alameda County protocol. Intubations will be confirmed by colorimetric capnometer or waveform capnography, and the esophageal detection device. Medics will perform conventional CPR according to current 2005 AHA Guidelines and will attach the ResQPOD circulatory enhancement device between the bag valve and mask, bag valve and tracheal tube or bag valve and Combitube. The device should be removed upon the return of spontaneous circulation (ROSC), but may / should be replaced if the patient subsequently loses pulses.

Hospital arrival:

The ResQPOD should remain in place until the patient's care is assumed by hospital personnel. The attending paramedic should make hospital medical personnel aware of the ResQPOD and particularly, its need to be removed upon resumption of pulses. All hospital respiratory therapy departments and emergency department physicians and nurses have received information regarding the ResQPOD and the pilot study.

Optimal CPR:

Optimal CPR according, to the American Heart Association, should be preformed at all times. The Res-Q-POD has a timing light which is useful in the intubated patient. Care should be taken to avoid hyperventilation, to start CPR immediately, to avoid interruptions, and to push hard (1 ½-2"), push fast (100x per minute), and to allow complete chest wall recoil.

Results and Data Collection:

The following data will be collected on ResQPOD patients:

- Name
- Sex
- age
- run #
- date
- time of arrest
- time of first CPR
- time of defibrillation (if applicable)
- initial rhythm
- subsequent rhythms (list)

- initial colorimetric capnometry or waveform capnography / ETCO2 in mmHg values
- subsequent changes in ETCO2 values (list)
- return of spontaneous circulation (ROSC) (Y,N) at hospital arrival
- admission to hospital
- survival (lived, died, transfer)

Patient Care Report Forms with a data summery sheet will be submitted by both Fire Departments on a monthly basis to the EMS agency. The trial study's major focus is to demonstrate the effectiveness, safety and ease of use of the device. However, researchers will track survival rates; although, the study is not powered to the sufficient degree to allow a meaningful result regarding survival from hospital.

Alameda County and Hayward Fire Departments EMS personnel and the county medical director will review each data form. Data will be entered in an access database. Appropriate statistical analysis will be performed.

Alameda County EMS will receive monthly reports from the providers who are performing the trial study. Alameda County EMS will secure data from hospitals regarding outcome. Provider personnel are to notify Dr. Pointer immediately if there are any patient safety concerns. The study will be presented to the Alameda County Medical Centers/ Department of Public Health Human Subjects Protection Committee. All records will be maintained in a locked file which can be accessed only by the EMS medical director. Federal guidelines regarding implied consent for arrested patients will be followed.

RES Q POD DATA SHEET

Patient Name	Sex	Age	Run Number, ID	Date	Time of Arrest (Approx)	Time of First CPR	Time of Defibrillation (If Applicable)	Initial Rhythm	Subsequent Rhythm (s) (List)	Initial ETCO2 (color or mmHg)	ETCo2 Changes (color or mmHg)	ROSC (y,n) Prior to Hospital Arrival	Hospital	Attach PCR Survival Live Dead Transfer